# Mazindol Granted Orphan Drug Designation in the US & Europe for Treatment of Narcolepsy

## Milestone achievement in the development of a wake-promoting agent for a lifelong sleep disorder

Stans/Switzerland, July 11, 2016 – NLS Pharma Group (NLS) announced that the US Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) for Mazindol for the treatment of narcolepsy. On October 9, 2015, an ODD was granted by the European Commission to NLS for Mazindol within the same indication. ODD provides incentives such as tax credits, user fee waivers and eligibility for orphan drug exclusivity to assist and encourage the development of drugs for rare diseases.

Alex Zwyer, CEO of NLS Pharma: "The US ODD for Mazindol for the treatment of narcolepsy marks yet another major development milestone for our lead compound. Mazindol has been used off-label in narcolepsy since the 1970's, and it is our goal to make it available to all narcoleptic patients."

### About Narcolepsy

Narcolepsy is a chronic, debilitating neurological disease, the primary symptoms of which are excessive daytime sleepiness (EDS), fragmented nighttime sleep, sleep paralysis and cataplexy. The hallmark symptom of narcolepsy is excessive and overwhelming daytime sleepiness, even after nighttime sleep. EDS is present in all narcolepsy patients and causes patients to become drowsy or fall asleep, often at inappropriate times and places. Cataplexy, the sudden loss of muscle tone, is the most predictive symptom of narcolepsy. Cataplexy can range from slight weakness or a drooping of the face to the complete loss of muscle tone and is triggered by strong emotional reactions such as laughter, anger or surprise. Narcolepsy is under-recognized and under-diagnosed, with approximately 3 million people suffering from this disease globally. Although narcolepsy is thought to affect around 150'000 - 200,000 Americans, only about 50,000 are currently being diagnosed.

## About Mazindol

Mazindol is a wake-promoting agent, a norepinephrine and dopamine reuptake inhibitor which was previously approved in Europe and in the US for the short term treatment of obesity. Rebalancing dysfunctional central nervous system (CNS) noradrenergic and dopaminergic systems appears to be critical for the effective treatment of ADHD and narcolepsy. Mazindol is NLS' lead compound for which US FDA has accepted an investigational new drug (IND) on June 9, 2016 for a phase II Proof-of-Concept clinical trial evaluating the use of Mazindol in adults with Attention Deficit Hyperactivity Disorder (ADHD).

## About NLS Pharma

NLS/NLS-0/NLS-1 Pharma (NLS) – NLS is a Swiss based biotech group focusing on the repurposing of established and (cost-) effective drug/chemical compounds to treat ADHD, sleep disorders and cognitive impairment.

NLS is a fully privately owned enterprise managed by a top level team of experts who have proven their value and experience with Big Pharma companies. They work closely with renowned AD-HD and sleep related disorders opinion leaders.

Series-A financing was successfully completed for $ 8.5 million on August 31, 2015, to secure proof of concept of mazindol in ADHD.

## Media, Investor relations & partnering contact

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